DEPARTMENT OF HEALTH & HUMAN SERVICES

#13

Public Health Service

Food and Drug Administration
Rockville MD 20857

99 MAY 12 AM 9:49

ASSISTANT COMMISSIONER
FOR PATENTS

MAY - 5 1999

Re: Omnicef® Tablets
Docket No.: 98E-0754

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,559,334, filed by Warner-Lambert Company, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Omnicef® Tablets, the human drug product claimed by the patent.

The total length of the regulatory review period for Omnicef® Tablets is 2,745 days. Of this time, 2,288 days occurred during the testing phase and 457 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 1, 1990.

   FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on June 1, 1990.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 4, 1996.

   FDA has verified the applicant's claim that the new drug application (NDA) for Omnicef® Tablets (NDA 50-739) was initially submitted on September 4, 1996.

3. The date the application was approved: December 4, 1997.

   FDA has verified the applicant's claim that NDA 50-739 was approved on December 4, 1997.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Charles W. Ashbrook
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